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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,432	08/19/2003	Kenneth W. Dobie	ISPH-0758	4420

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,432	DOBIE ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of gene expression with antisense oligonucleotides in cells *in vitro*, does not reasonably provide enablement for antisense inhibition of gene expression in cells or tissues *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

1. Claim 14 is drawn to a method of inhibiting expression of KOX 1 in cells or tissues by contacting the cells with an antisense oligonucleotide. This claim encompasses both embodiments where the cells or tissue are in an organism as well as embodiments where the cells or tissues are not in an organism. The specification

provides on pages 36-40 general routes of delivery to organisms and dosage forms that can be used to formulate antisense oligonucleotides as therapeutic agents. The specification does not describe how to administer antisense oligonucleotides to any organism such that the oligonucleotide enters the cells of the organism in a sufficient concentration and remains active for a sufficient period to time to inhibit expression of KOX 1.

2. The state of the art prior art is such that inhibition of gene expression *in vitro* is routine, but *in vivo* inhibition of gene expression at the time of filing and even to the present time is not routine for several reasons, including the problems of delivery, specificity and duration.

3. The problems of nucleic acid based therapies and antisense technology are well known in the art, particularly with regard to the inability to specifically deliver an effective concentration of a nucleic acid to a target cell, such that a target gene is inhibited to a degree necessary to result in a therapeutic effect. For example, at the time the instant invention was made, the therapeutic use of nucleic acids was a highly unpredictable art due to obstacles that continue to hinder the therapeutic application of nucleic acids *in vivo* (whole organism) (see for example Agrawal et al. (Molecular Medicine Today, 2000, vol 6, p 72-81), Jen et al. (Stem Cells 2000, Vol. 18, p 307-319) and Opalinska et al. (Nature Reviews Drug Discovery, 2002, vol 1, p. 503-514)). Such obstacles include, for example, problems with delivery, target accessibility and the potential for unpredictable nonspecific effects.

4. Jen et al. state (see page 313, second column, second paragraph) "One of the major limitations for the therapeutic use of AS-ODNS and ribozymes is the problem of

delivery....presently, some success has been achieved in tissue culture, but efficient delivery for *in vivo* animal studies remains questionable". Jen et al. outlines many of the factors limiting the application of antisense for therapeutic purposes and concludes (see p 315, second column), "Given the state of the art, it is perhaps not surprising that effective and efficient clinical translation of the antisense strategy has proven elusive."

5. Opalinska et al. (Nature Reviews Drug Discovery, 2002, vol 1, p. 503-514) state "[I]t is widely appreciated that the ability of nucleic-acid molecules to modify gene expression *in vivo* is quite variable, and therefore wanting in terms of reliability. Several issues have been implicated as a root cause of this problem, including molecule delivery to targeted cells and specific compartments within cells and identification of sequence that is accessible to hybridization in the genomic DNA or RNA" and in column 2 of the same page, "Another problem in this field is the limited ability to deliver nucleic acids into cells and have them reach their target. Without this ability, it is clear that even an appropriately targeted sequence is not likely to be efficient. As a general rule, oligonucleotides are taken up primarily through a combination of adsorptive and fluid-phase endocytosis. After internalization, confocal and electron microscopy studies have indicated that the bulk of the oligonucleotides enter the endosome-lysosome compartment, in which most of the material becomes either trapped or degraded."

6. Given this unpredictability, the skilled artisan would require specific guidance to practice the claimed methods *in vivo* in all organisms, with a resultant inhibition of gene expression, as claimed. The specification provides examples of inhibition of KOX 1 expression in several human cell lines, however, cell culture examples are generally not predictive of *in vivo* inhibition and the methods of delivery of the exemplified cell line

would not be applicable to delivery of oligonucleotides to any organism. Often formulations and techniques for delivery *in vitro* (cell culture) are not applicable *in vivo* (whole organism) (see for example Jen et al., page 313, second column, second paragraph). For example, Agrawal et al. (see p 79-80, section entitled "Cellular uptake facilitators for *in vitro* studies") states "The cellular uptake of negatively charged oligonucleotides is one of the important factors in determining the efficacy of antisense oligonucleotides.....*In vitro*, cellular uptake of antisense oligonucleotides depends on many factors, including cell type, kinetics of uptake, tissue culture conditions, and chemical nature, length and sequence of the oligonucleotide. Any one of these factors can influence the biological activity of an antisense oligonucleotide." Due to differences in the physiological conditions of a cell *in vitro* versus *in vivo*, the uptake and biological activity observed *in vitro* would not predictably translate to *in vivo* results.

7. Given these teachings, the skilled artisan would not know *a priori* whether introduction of antisense oligonucleotides *in vivo* by the broadly disclosed methodologies of the instant invention, would result in successful inhibition of expression of a target gene. One of skill in the art would not know how to deliver oligonucleotides to an organism in such a way that would ensure an amount sufficient to modify or inhibit expression of a target gene is delivered to the proper cell.

8. In fact, the state of the art is such that successful delivery of oligonucleotide sequences *in vivo* or *in vitro*, such that the polynucleotide or oligonucleotide provides the requisite biological effect to the target cells/tissues/organs, must be determined empirically. Methods of inhibiting gene expression using nucleic acids *in vivo* are unpredictable with respect to delivery of the nucleic acid molecule such that the nucleic

acid molecule is targeted to the appropriate cell/organ, at a bioeffective concentration and for a period of time such that the nucleic acid molecule is effective in, as in the instant application, attenuating or inhibiting expression of a target gene.

9. The specification does not provide the guidance required to overcome the art-recognized unpredictability of using antisense oligonucleotides in therapeutic applications in any organism. The field of antisense therapeutics does not provide that guidance, such that the skilled artisan would be able to practice the claimed therapeutic methods.

10. Thus, while the specification is enabling for the examples set forth in the specification, the specification is not enabling for antisense inhibition of the expression of KOX 1 in cells or tissues of any organism *in vivo* as the art of inhibiting gene expression by introducing antisense oligonucleotides into an organism is neither routine nor predictable. In order to practice the claimed invention *in vivo* in all organisms a number of variables would have to be optimized, including 1). the mode of delivery of the antisense or oligonucleotide to an organism that would allow it to reach the targeted cell, 2). the amount of antisense or oligonucleotide that would need to be delivered in order to bind a sufficient amount of KOX 1 to modulate gene expression once it reached the proper cell and 3). ensuring the antisense oligonucleotide remains viable in a cell for a period of time that allows modulation of gene expression to an extent that there is a measurable and significant effect. Each one of these variables would have to be empirically determined for each antisense oligonucleotide. While optimization of any single one of these steps may be routine, when taken together the amount of experimentation required becomes such that one of skill in the art could not practice the

invention commensurate in scope with the claims without undue, trial and error experimentation and therefore, claim 14 is not enabled.

Claim Rejections - 35 USC § 102 and 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 35 USC 103 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cowsert (US 6,107,092).

Claim 1 is drawn to an oligonucleotide 8 to 80 bases in length that specifically hybridizes to the coding region of a nucleic acid that encodes KOX 1 and inhibits the expression of KOX 1. Claim 2 limits claim 1 by stating the oligonucleotide is an

antisense oligonucleotide. Claims 3-9 limit claim 2 by stating the antisense oligonucleotide can comprise a modified linkage that may be a phosphorothioate, a modified sugar moiety where the modification may be methoxyethyl, a modified nucleobase that may be 5-methylcytosine or can comprise a chimeric oligonucleotide. Claim 11-13 are drawn to compositions of the compound of claim 1 where the compound may be an antisense oligonucleotide and can further comprise a colloidal dispersion system. Claim 14 is directed to a method of inhibiting expression of KOX 1 in cells or tissues using the compound of claim 1.

11. Cowsert discloses antisense oligonucleotides targeted to SRA that include an oligonucleotide 18 bases long designated as SEQ ID NO: 70 that hybridizes to nucleotides 1489-1506 of the nucleic acid encoding KOX 1 (SEQ ID NO: 12). Cowsert discloses at column 5 line 19 through column 9, line 54 that antisense oligonucleotides targeted to SRA can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At columns 16-20 Cowsert discloses that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 11, lines 50-53 that the compositions are formed with pharmaceutically acceptable carriers. Although the oligonucleotide of Cowsert is not disclosed as specifically hybridizing to a nucleic acid molecule encoding KOX 1, the oligonucleotide of Cowsert is the complement of nucleotides within SEQ ID NO: 12 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding KOX 1 as per applicant's definition set forth in the specification as filed, see page 14, lines 7-21.

12. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

13. Thus, Cowsert discloses all limitations of and anticipates claims 1-9 and 11-14.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dean et al. (US 5,985,558).

14. Claim 1-9 and 11-14 are described in the previous 102 rejection. Dean et al. disclose antisense oligonucleotides targeted to c-Jun and c-Fos that include an oligonucleotide 20 bases long designated as SEQ ID NO: 125 that hybridizes to nucleotides 1290-1308 of the nucleic acid encoding KOX 1 (SEQ ID NO: 12). Dean et al. disclose at column 7 line 63 through column 10, line 62 that antisense oligonucleotides targeted to c-Jun and c-Fos can comprise modified linkages including

phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At column 15, line 62 through column 16, line 65 Dean et al. disclose that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 11, lines 45-49 that the compositions are formed with pharmaceutically acceptable carriers. Although the oligonucleotide of Dean et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding KOX 1, the oligonucleotide of Dean et al. is the complement of nucleotides within SEQ ID NO: 12 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding KOX 1 as per applicant's definition set forth in the specification as filed, see page 14, lines 7-21.

15. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic.

Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

16. Thus, Dean et al. disclose all limitations of and anticipate claims 1-9 and 11-14.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weber et al. (US 6,306,606).

17. Claims 1-9 and 11-14 are described in a previous 102 rejection. Weber et al. disclose antisense oligonucleotides targeted to MP-1 that include an oligonucleotide 18 bases long designated as SEQ ID NO: 100 that hybridizes to nucleotides 514-531 of the nucleic acid encoding KOX 1 (SEQ ID NO: 12). Weber et al. disclose at column 5 line 21 through column 9, line 31 that antisense oligonucleotides targeted to MP-1 can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At columns 16-20 Weber et al. disclose that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 11, lines 27-30 that the compositions are formed with pharmaceutically acceptable carriers. Although the oligonucleotide of Weber et al. is not disclosed as specifically hybridizing to a nucleic acid molecule encoding KOX 1, the oligonucleotide of Weber et al. is the complement of nucleotides within SEQ ID NO: 12 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding KOX 1 as per applicant's definition set forth in the specification as filed, see page 14, lines 7-21.

18. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

19. Thus, Weber et al. discloses all limitations of and anticipates claims 1-9 and 11-14.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cowsert (US 6,566,131).

20. Claims 1-9 and 11-14 are described in a previous 102 rejection. Cowsert discloses antisense oligonucleotides targeted to SMAD6 that include an oligonucleotide 18 bases long designated as SEQ ID NO: 25 that hybridizes to nucleotides 1033-1050 of the nucleic acid encoding KOX 1 (SEQ ID NO: 12). Cowsert discloses at column 5 line 40 through column 11, line 16 that antisense oligonucleotides targeted to SMAD6

can comprise modified linkages including phosphorothioates, modified sugar moieties including methoxyethyl, modified nucleobases including 5-methylcytosine and that such oligonucleotides can be chimeras. At columns 19-23 Cowsert discloses that the oligonucleotides can be made into compositions with liposomes, a colloidal dispersion system and at column 24, line 63 through column 25 line 18 that the compositions are formed with pharmaceutically acceptable carriers. Although the oligonucleotide of Cowsert is not disclosed as specifically hybridizing to a nucleic acid molecule encoding KOX 1, the oligonucleotide of Cowsert is the complement of nucleotides within SEQ ID NO: 12 of the instant application and would therefore be expected to "specifically hybridize" to a nucleic acid encoding KOX 1 as per applicant's definition set forth in the specification as filed, see page 14, lines 7-21.

21. Furthermore, since the prior art oligonucleotides meet all the structural limitations of the claims, the prior art oligonucleotides would then be considered to "inhibit expression" of the gene as claimed, absent evidence to the contrary. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic.

Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims."

22. Thus, Cowsert discloses all limitations of and anticipates claims 1-9 and 11-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
April 12, 2005

JAMES SCHULTZ
PATENT EXAMINER